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Attorney for Plaintiff Michael Smith

MONTANA FOURTH JUDICIAL DISTRICT COURT,
MISSOULA COUNTY

MICHAEL SMITH	)	Hon._____
	)	Cause No.:_____
Plaintiff,	)	Dept. No.:_____
	)	
-vs-	)	
	)	
WRIGHT MEDICAL GROUP, INC.; WRIGHT MEDICAL TECHNOLOGY, INC.; and DOES 1-10.	)	**COMPLAINT AND DEMAND FOR JURY TRIAL**
	)	
Defendants.		

Plaintiff Michael Smith alleges as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff Michael Smith is, and at all relevant times herein, has been a Montana citizen and a resident of the City of Missoula in Missoula County, Montana.

2. Defendant Wright Medical Group, Inc., upon information and belief,

is and was at all times relevant to this Complaint a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business in Tennessee.

3. Defendant Wright Medical Technology, Inc., upon information and belief, is a subsidiary of Wright Medical Group, Inc., and at all times relevant to this Complaint was a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business located in Tennessee.

4. Does 1-10 are other persons or entities, yet to be identified, who may be liable for the damages alleged herein for any reason, including but not limited to their involvement in the design, manufacture, sale, distribution, marketing, inspection or maintenance of the subject hip implant device components.

5. At all times relevant to this Complaint, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendant(s). Defendants, therefore, are subject to joint and several liability.

6. This Court has personal jurisdiction pursuant to Montana's Long Arm Rule, Mont. R. Civ. P. 4(b), and the Due Process Clause of the U.S. Constitution.

Defendants designed, manufactured, produced, made, marketed, distributed and/or sold medical device products which were used by Plaintiff. Defendants were at all times relevant herein doing business in and/or having directed their activities at the State of Montana and Missoula County, including advertising, selling, and delivering the products at issue in Missoula County, Montana. Defendants' conduct and connections in Montana are such that it has established sufficient minimum contacts with the State of Montana, should reasonably anticipate being sued in Montana, and maintenance of this suit does not offend traditional notions of fair play and substantial justice.

7. This Court has jurisdiction.

8. The implant device was sold and implanted in Missoula County, Plaintiff lives in Missoula County, and Plaintiff has undergone medical care and treatment in Missoula County. Missoula County is a proper venue. Mont. Code Ann. § 25-2-122(2)(a) and (b).

ALLEGATIONS COMMON TO ALL COUNTS

9. At all times relevant to this Complaint, Defendants were involved in the design, manufacture, marketing sale, and/or distribution of medical device products, including the Profemur hip implant system and components at issue in this case.

10. The hip implant system components at issue are a Profemur modular neck and stem system. All defective components implanted in Plaintiff were designed, manufactured, marketed and sold by Defendants.

11. Upon information and belief Defendants were able to avoid a lengthy and expensive FDA approval process for the Profemur hip system by representing that the devices were similar to other hip implant systems that had been used for some time.

12. Defendants knew that there were reports of problems with the Profemur hip replacement system and components at issue which included corrosion, fretting, wear, and complete failure of the femoral neck and stem. Such problems were reported to Defendants predecessor, Wright Cremascoli, the United States Food and Drug Administration, the Australian Joint Registry, and joint registries in other countries. Defendants knew that there were higher fracture rates with its Profemur components. Despite ongoing fractures defendants misrepresented fracture rates, the safety of its Profemur devices, and refused to recall the inherently unsafe devices or inform people who had Profemur implants about increasing fractures of devices made after 2000.

13. Surgeons from the University of Michigan studied the results of the Profemur line of hip replacements from 2003-2009. The authors reported failure

rates of the Profemur line greater than 15%. Bimodular neck fracture was common. *See* "High Risk of Failure with Bimodular Femoral Components in THA," *Clin. Orthop. Relat. Res.* (2016) 474: 146-153.

14. Plaintiff has been a very active person all of his life. The ability to continue being active was a reason he decided to have hip replacement surgery.

15. In 2004 Plaintiff and Dr. Willstein discussed a hip replacement with a newer system that had been marketed by Wright Medical. At that time hip pain was interfering with his job and activities, including related to sports and golf. Plaintiff understood that the device would last 25 to 30 years. He was not warned about and has never been warned about the high fracture rates of Defendants' Profemur devices.

16. Defendants advertised and marketed the Profemur components as being particularly well suited for active people.

17. In 2004, Dr. Willstein performed a right total hip replacement surgery on Plaintiff using a Wright Profemur system and other Wright components. The surgery went well. After the surgery Plaintiff was pain free and returned to most of his activities.

18. Before and after Plaintiff's operation, Wright was regularly notified about problems including corrosion, fretting and fractures of the same or similar

Profemur devices. Wright failed to notify Plaintiff or other similarly situated people of the increasingly high rates of fractures in its Profemur hip implant devices.

19. On April 1, 2020, Plaintiff was doing his regular morning walk while on vacation in Arizona. He felt something clunk or move, took one more step, felt a severe jolt in his groin and fell. He was out of cell coverage, could not get up, and could not call for help. A good samaritan found him and called 911. Plaintiff was taken by ambulance to the hospital in Gilbert, Arizona. X rays showed a right femoral neck catastrophic fracture at the junction of the femoral stem component with the femoral neck. Records state the fracture caused dislocation and displacement of his hip joint. The fracture was in the femoral neck/stem modular junction.

20. Plaintiff was hospitalized for a week during the COVID pandemic. He underwent a complicated hip revision surgery on April 3, 2020. Due to the complexity Plaintiff's femur had to be broken in several places and an extended trochanteric osteotomy was done.

21. The Wright Profemur system had to be removed and replaced with implant components from different manufacturers. During surgery, there was considerable difficulty removing the femoral component from the femoral canal.

22. Plaintiff has suffered severe and ongoing pain. The surgeon had to cut down and remove about one third of the lateral femur. Since the operation Plaintiff is continuing with physical therapy, rehabilitation, and medical appointments.

23. As a result of the failure of the Profemur components, Plaintiff has suffered significant harm, including but not limited to physical injury and bodily impairment, surgery and medical treatment, mental pain and suffering, inability to engage in his normal activities, medical bills, future medical expenses and other special and general damages as allowed by law.

CLAIMS FOR RELIEF

COUNT I- STRICT PRODUCT LIABILITY

24. Plaintiff hereby incorporates all other paragraphs of this Complaint as though fully set forth herein.

25. Defendants intended the Profemur components at issue, which were designed, manufactured, produced, assembled, made, marketed, distributed and/or sold by them, to be used as a hip replacement system.

26. The Profemur system and components at issue here were defective, unreasonably dangerous and unsafe for their intended purpose. The components reached Plaintiff, a user or consumer, without substantial change in the condition

in which they were sold.

27. The Profemur hip replacement system and components were defective, unreasonably dangerous and unsafe for their intended purpose due to their design, manufacture and/or Defendants' failure to warn of dangers that would not be readily recognized by the ordinary user. Due to such defects, the devices were unsafe and unfit for their intended use.

28. The Profemur hip replacement system and components failed to perform safely under ordinary and anticipated use. After recovery from surgery and regular use, the Profemur hip replacement system suffered a complete and catastrophic failure, with the neck breaking in half, requiring a revision surgery.

29. Defendants put into the stream of commerce and promoted devices which were defective and in an unreasonably dangerous condition for their intended or foreseeable use and known to have the propensity to wear out and fracture due to Defendants' modular design.

30. The Profemur components were also in a defective condition because Defendants failed to adequately warn patients and medical professionals of the existing dangers associated with their Profemur device and the increasing problems thereafter which occurred every year before and after Plaintiff's device was implanted. Had defendants provided adequate warnings, Plaintiff would not

have agreed to have it implanted or required a dangerous and complicated operation because of the fracture which damaged his hip joint.

31. Plaintiff used the Profemur components for their intended purpose and in a reasonable manner.

32. The defective nature of the devices caused injury and damages to Plaintiff.

COUNT II- FAILURE TO WARN

33. Plaintiff hereby incorporates all other paragraphs of this Complaint as though fully set forth herein.

34. Defendants knew or should have known that the devices at issue were defective and unreasonably dangerous when being used for their intended purpose.

35. Defendants knew or should have known that the devices at issue could fail, and that use of the products involved a danger for which Defendants were required to warn consumers. Defendants further knew or should have known of the risks associated with early wear, corrosion, and failure. There were reports of fretting, fracture and early failure of the Profemur components which Defendants cancealed.

36. Defendants had a duty to warn users and consumers of the dangerous condition of the devices because the dangers were not open or obvious to the

consumer or user.

37. If Plaintiff had been adequately warned of the risks related to implantation of the Profemur components, including the risk of catastrophic and complete device failure, he would not have consented to implantation of Defendants' Profemur hip replacement system.

38. Defendants were obligated to provide post-sale warnings to users of its devices. Defendants failed to provide adequate warnings to Plaintiff at any time, including after Defendants knew about hundreds of failures of its Profemur hip replacement system.

39. As a result of Defendants' failure to warn, the devices continued to be implanted in patients such as Plaintiff.

40. Defendants' breaches of their duty to warn caused injuries and losses to Plaintiff as alleged herein.

COUNT III- BREACH OF WARRANTY

41. Plaintiff hereby incorporates all other paragraphs of this Complaint as though fully set forth herein.

42. Prior to the time that Plaintiff used the Profemur hip implant components for their intended purpose, Defendants expressly and impliedly warranted that the products were of merchantable quality and reasonably fit and

safe for their ordinary use and intended purpose.

43. Defendants knew or should have known the particular purpose for which the goods were required and that Plaintiff and other consumers were relying upon Defendants' skill and judgment to provide suitable goods.

44. In a reasonable and foreseeable manner, Plaintiff relied on Defendants' express and implied representations and warranties in consenting to hip replacement surgery with Defendants' devices.

45. Defendants breached their express and implied representations and warranties regarding the safety and merchantability and fitness for a particular purpose of their devices.

46. The subject devices were not safe, not fit for their intended use, nor of merchantable quality as warranted by Defendants.

47. Defendants knew or had reason to know that the subject devices were not safe, not fit for their intended use, nor of merchantable quality as warranted by Defendants.

48. Defendants' knowledge included, but was not limited to, that there had been reports of early failures related to the Profemur hip implant components, that the Profemur components suffered early fretting, corrosion, and complete failure at a higher rate than other devices.

49. As a result of Defendants' breach of warranties, Plaintiff has suffered injuries, losses, and damages recoverable herein.

COUNT IV- CONSUMER PROTECTION ACT

50. Plaintiff hereby incorporates all other paragraphs of this Complaint as though fully set forth herein.

51. At all times relevant to this action, the Montana Consumer Protection Act, Mont. Code Ann. §§ 30-14-101 *et seq.* precluded "unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. § 30-14-103. Defendants herein were involved in the trade, commerce, sale, marketing, advertising and promoting of Profemur devices as particularly suited for active people like Plaintiff.

52. An unfair act or practice includes one that offends public policy and which is either immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.

53. Plaintiff purchased the Profemur hip component parts for personal use.

54. Defendants marketed, distributed, and sold the Profemur hip replacement system to consumers and doctors in the State of Montana and city of Missoula. Several Montana consumers have suffered injuries from the

catastrophic failure of Defendants' Profemur modular hip implant system. Defendants' acts constitute acts of trade or commerce that impacted consumers in the State of Montana.

55. Upon information and belief, the Defendants' unfair or deceptive acts or practices include, but are not limited to, fraudulent concealment and knowing and false representations of material facts to consumers. Defendants concealed known dangers. Defendants misrepresentations continued after they knew of increasing problems with hundreds of fractures and after facing numerous lawsuits. Instead of informing consumers, defendants made misrepresentations to regulators and courts around the country regarding the safety of the same or similar Profemur devices. Additional violations include the failure to timely alert consumers of the problems and risks which were discovered regarding the Defendants' hip implant systems. Defendants' deceptive and unfair acts were made for the purpose of procuring and promoting the sale of the Profemur system and other similar components and continuing to gain economically at the expense of Plaintiff and other similarly situated consumers in Montana.

56. Defendants allowed defective and unreasonably dangerous hip implant components to be implanted despite substantial indications they could fail, necessitating additional surgeries and interventions.

57. Defendants misled consumers and misrepresented the efficacy and reliability of the devices.

58. Defendants failed to take steps to warn about the risk of failure of such devices.

59. Defendants' representations, omissions and practices were likely to mislead the average patient/consumer and, in fact, misled Plaintiff and his doctor, including into believing that Defendants' devices at issue were safe and reliable.

60. Defendants' overall conduct constitutes an unfair and deceptive practice.

61. As a result of Defendants' unfair and deceptive trade practices, Plaintiff suffered actual damages as set forth herein for which he is entitled to compensation under the Consumer Protection Act, including treble damages, attorney fees, and costs. Mont. Code Ann. § 30-14-133.

COUNT V- NEGLIGENCE

62. Plaintiff hereby incorporates all other paragraphs of this Complaint as though fully set forth herein.

63. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, sale and distribution into the stream of commerce of the Profemur hip implant system and component parts, including a duty to

ensure that the device did not pose a significantly increased risk of adverse events and to warn consumers about them.

64. Defendants failed to exercise reasonable care in the design, manufacture, testing, marketing, sale and distribution into the stream of commerce, and failed to adequately and timely warn physicians and patients regarding the risks and dangers associated with the Profemur device and component parts.

65. Despite the fact that Defendants knew or should have known of adverse risks, such as early failure and the disintegration of its hip replacement system components, Defendants continued to manufacture, market, sell and distribute the Profemur and other similar components as a safe and effective hip replacement system. With knowledge of increasing numbers of fractures Defendants chose to misrepresent the nature of the problems, fracture rates, and mislead the public.

66. As a direct and proximate result of Defendants' negligence Plaintiff has suffered and will suffer damages, including, but not limited to, physical injury and bodily impairment, lack of mobility, pain and suffering, significant medical bills, loss of earnings, altered way of life and lifestyle, future and special medical damages, and other special and general damages.

PUNITIVE DAMAGES

67. Plaintiff hereby incorporates all other paragraphs of this Complaint as though fully set forth herein.

68. Defendants' conduct, as described herein, constitutes actual fraud and actual malice as defined in Mont. Code Ann. § 27-1-221.

69. Defendants' conduct was performed in conscious and intentional disregard of, and indifference to, the high probability of injury to patients, including Plaintiff. Defendants engaged in a pattern of concealing and misrepresenting known safety hazards and fracture rates despite a high risk of injury and damage to Plaintiff and other similar users of the Profemur hip implant system and components. Defendants made repeated misrepresentations about the safety of its Profemur device, its propensity to injury people, and the actual rates of fracture to patients throughout the United States and in other countries.

70. Defendants' knew or should have known that other similarly situated people in Montana and other states would continue to suffer fractures. Instead of informing Plaintiff or others about the hazards, defendants spent enormous sums of money trying to cover up and conceal the problems and made misrepresentations to the public. Defendants' conduct as alleged herein and to be proven at trial demonstrates reckless disregard for the safety, health and well-

being of Plaintiff and other similarly situated people so as to justify punitive damages in the maximum amount allowed by Montana law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests:

1. All damages for past and future medical expenses, economic losses, pain and suffering, emotional distress, loss of household services and other general and special damages to the full extent allowed by law;
2. For treble damages, costs and attorneys' fees pursuant to Mont. Code Ann. § 30-14-133;
3. For punitive damages; and
4. Such other relief as permitted by law or deemed just and equitable by the Court.

JURY DEMAND

Plaintiff requests a jury trial on all matters appropriately tried to a jury.

Dated this 24th day of September, 2020.

James T. Towe
TOWE & FITZPATRICK, PLLC

Attorney for Plaintiff Michael Smith